

PSJ14 Janssen Opp Exh 57 – JAN-MS-03741170

Work Instruction	
Status: Superseded	Effective Date: N/A
Title: JOM Customer Service Suspicious or Excessive Narcotic Orders	
Doc. No. PSGA-DOC-45016	Version: 1.0

1.0 Purpose

- 1.1 To define a process that complies with the DEA requirement to provide information on controlled substance orders considered potentially suspicious or excessive.

2.0 Scope

- 2.1 The scope of this work instruction is to cover identifying and tracking potentially suspicious or excessive narcotic orders.

3.0 References/Related Documents

- 3.1 PSGA-DOC-42786, JOM Customer Service Order Processing (VA01)
- 3.2 PSGA-DOC-42925, JOM Customer Service 10 Step Order Accuracy List
- 3.3 PSGA-DOC-7769, JOM Customer Service DPDP Execution & Customer Communication Process
- 3.4 Records Management Program for the Global J&J Pharma sector at <http://gis.prius.inj.com/recmgt/>
- 3.5 PSGA-DOC-44317, JOM Customer Service Order Processing of Controlled Substances
- 3.6 PSGA-DOC-45416, JOM Customer Service Schedule II Demand Adjustment Form

4.0 Definitions

- 4.1 SAP R/3 is the order-to-cash system used to process customer orders.
- 4.2 DEA - Drug Enforcement Administration
- 4.3 DPDP – Direct Purchasing & Distribution Policy

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4.4 DPDP Daily Exception Report – Report that automatically identifies orders where the ordered quantity requested exceeds the permitted quantity allowed.

4.5 RMD - Raw Mean Demand is a calculation provided by the DPDP Open Order Daily Exception Report, and is a representation of the historical weekly order average over a 52-week period.

5.0 Responsibilities

5.1 It is the responsibility of the DPDP Coordinator to follow this work instruction for identifying potentially suspicious or excessive narcotic orders.

5.2 It is the responsibility of the Customer Service Team Leader to ensure this work instruction is followed.

5.3 It is the responsibility of the JOM QA Representative to report any potentially suspicious or excessive narcotic orders to the DEA as identified by this process.

6.0 Safety and Environmental Practices

6.1 N/A

7.0 Equipment/Materials

7.1 SAP R/3 Order Processing Database

7.2 Business Warehouse Reports

8.0 Procedure

8.1 Identifying potentially Suspicious or Excessive Narcotic Orders (Schedule II & III)

8.1.1 Generate the DPDP Open Orders Daily Exception Report (reference PSGA-DOC-7769, JOM Customer Service DPDP Execution & Customer Communication Process). Sort and separate Schedule II and Schedule III product information and then paste data onto an electronic worksheet. Note the date it was created. Title the worksheet "Controlled Substance Order Alert."

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- 8.1.2 Divide the Order Quantity by the RMD (Raw Mean Demand) for each Schedule II and Schedule III product to determine percent variance based on historical data and transfer this information onto the Controlled Substance Order Alert worksheet.
- 8.1.3 Sort the data according to the % variance value.
- 8.1.4 Highlight any order with a % variance value greater than 3x the customer's average order over a 52-week period.
- 8.1.5 For all narcotic orders that are viewed as potentially suspicious or excessive, the customer will be contacted via telephone by a Schedule II Team Member to request an explanation for the increased demand and change in order pattern utilizing the Schedule II Demand Adjustment form.
- 8.1.6 Customer Service is to adhere to the following script when contacting the customer:
 - 8.1.6.1 "JOM is committed to complying with all DEA guidelines and regulations. Part of that commitment requires us to identify suspicious or excessive orders and notify the DEA accordingly. We have noticed this week's order has exceeded your normal demand by X%. Please provide the reason for your increase in demand on the Schedule II Demand Adjustment Form. Again, this request is to ensure compliance with the DEA."
- 8.1.7 The Schedule II Team Member will enter all customer information on the Schedule II Demand Adjustment form and provide to the customer via fax or email.
- 8.1.8 The customer will sign and return the Schedule II Demand Adjustment form noting a detailed explanation for the increase in demand.
- 8.1.9 The Schedule II Team Member will note the customer explanation on the Controlled Substance Order Alert worksheet.

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8.1.10 Should the customer refuse to provide an explanation for the increase in demand or fail to return the completed Schedule II Demand Adjustment form, the Schedule II Team Member will explain to the customer that the order cannot be shipped until clearance is received from a JOM QA Representative.

8.1.11 The Controlled Substance Order Alert worksheet and the Schedule II Demand Adjustment form will be saved twice daily in the Schedule II Team shared drive (L-drive) as well as forwarded electronically to a JOM QA Representative so that it can be reviewed to determine which orders are potentially suspicious or excessive. The URL for the file is:

\\na.jnj.com\psgusdfsroot\JOM\Customer Service\Teams\Schedule 2 team

8.1.12 The Controlled Substance Order Alert worksheet and the Schedule II Demand Adjustment form will be saved for a period of (2) two years.

8.1.13 A JOM QA Representative will review the Controlled Substance Order Alert worksheet and Schedule II Demand Adjustment form to determine if the customer's explanation for the increased demand and change in order pattern is an acceptable explanation. The JOM QA Representative will then determine which orders need to be reported to the DEA within one business day.

8.1.14 All orders on the Controlled Substance Order Alert worksheet will be held until the completed Schedule II Demand Adjustment form is received from the customer. JOM QA will advise the Schedule II Team Member via email as to which orders can be released for shipment based on the reason noted on the Schedule II Demand Adjustment form.

8.1.15 A JOM QA representative will sign the completed Schedule II Demand Adjustment Form and return it to Customer Service to be filed with the Controlled Substance Order Alert Worksheet.

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8.2 DEA Notification

- 8.2.1 The JOM QA Representative will notify the DEA via fax within one business day any orders have been identified as suspicious or excessive.
- 8.2.2 The JOM QA representative will provide the Controlled Substance Order Alert worksheet to the DEA on a bi-weekly basis noting all orders that have exceeded the permitted quantity by 3 times the normal mean demand and the reasons for the demand increase. (Refer to step 8.1.2)
- 8.2.3 The following documents will be stored in the Schedule II cabinet for a period of two (2) years for future review per the Records Management Program for the Global J&J Pharma sector, <http://gis.prius.jnj.com/recmgt/>
 - 8.2.3.1 Controlled Substance Order Alert worksheet
 - 8.2.3.2 JOM Customer Service Schedule II Demand Adjustment Form
 - 8.2.3.3 DEA Notification occurring same day
 - 8.2.3.4 DEA Notification occurring bi-weekly

9.0 Appendices/Attachments

- 9.1 N/A

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History of Change

Version Number	Change Control Number	Section	Reason for Revision (Description of Change)
1.0	CR-9017	All	Creating a new Work Instruction

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APPROVAL PAGE

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